Report on the Quality System Inspection Technique (QSIT) Study

April 26, 1999

Goals of the QSIT Study and Validation Activity

- **Decrease Time**
- **Increase Focus**
- **Move Towards Harmonization**
- **Ensure Quality Systems (QS) Regulation Coverage**

Outcomes of the QSIT Study and Validation Activity

- **Increase Consistency**
- **Improve Review Efficiency**

QSIT Validation

- **Protocols were used**
- **Data was assembled**
- **Reports developed**
- **Reported to QSIT Validation Work Group on March 18, 1999**

QSIT VALIDATION WORKSHEET

Item #	**Goal/Outcome**	
G1B (Activity 1)	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Term[1]	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
Short	Test	Total amount of time to conduct a comprehensive domestic Quality System Inspection
Scope and nature of the process to be followed.[2]	During a Study initiated on 10/1/98 and having a target completion date of 12/31/98, QSIT trained investigators in DEN-DO, LOS-DO and MIN-DO are to conduct comprehensive medical device Quality System inspections using the QSIT. A total of 12 trained investigators are participating in the Study. Each investigator is to conduct a target minimum of 4 QSIT inspections and report their QSIT related time per inspection on a CGCS (Form FDA 481A). Participating districts are to submit copies of the CGCSs to HFZ-332. Also, during the period 10/1/98 - 12/31/98, QSIT investigators from LOS-DO may be participating in a TURBO EIR pilot to evaluate the use of a computer program in streamlining the preparation of FDA 483s and EIRs. Beginning the week of 1/11/99, the average time for conducting comprehensive domestic QSIT inspections will be calculated using PODs data extracted from the subsystem database. Because the use of TURBO EIR may impact on the total inspectional time, LOS-DO inspections involving the use of TURBO EIR will not be included in this calculation. The average time for conducting QSIT inspections will be compared to the average time* for conducting comprehensive domestic Quality System inspections using the current approach. Overall responsibility for this activity: T. Wells (HFZ-332) and [illegible] (HFR-SW450) *Note: The average PODs reported time for conducting an inspection of a domestic medical device manufacturer using the current approach includes coverage of the Quality System regulation as well as the Medical Device Tracking Regulation. It will therefore be necessary to factor out the time spent covering the Tracking Regulation. This will yield the average inspectional time for conducting a comprehensive domestic Quality System inspection using the current approach. The average time spent covering the Tracking regulation will be determined by querying Device investigators as to the time spent covering Tracking on non-QSIT inspections and also through query of HFZ-305.	
Acceptance criteria (if known)	Decrease of total inspectional time.	
Extent to which the activity measures/confirms how well the goal/outcome has been met.[3] **(strengths and weaknesses of this validation activity)**	This activity will provide a direct and objective measurement of the total inspectional time using the QSIT. This activity will also provide an objective comparison of total inspectional time using the QSIT versus the current approach. The objective comparison will be limited by the need to adjust the average PODs reported time for conducting an inspection using the current approach in order to factor out the time that is included for covering the Tracking Regulation.	
Reason(s) why the activity represents one of the **best approaches** to measuring the accomplishment of the goal/outcome.	This pre-deployment activity objectively measures the satisfaction of the stated goal.	

Rev.12/18/98

[1] Short term = pre-deployment event, long-term = post-deployment event

[2] Describe who, what, where, when, and how. Include an identification of baseline data that may be useful for comparing QSIT performance to the existing approach.

[3] Include a discussion of any limitations in the ability of the activity to objectively measure the goal/outcome.

QSIT VALIDATION ACTIVITY REPORT

Item #	Goal/Outcome	
G1B	Decrease total time for conducting comprehensive domestic Quality System inspections of medical device manufacturers.	
Activity #	**Type of activity** (test or analysis)	**Parameter**(s) to be measured
1	Test	Total amount of time to conduct a comprehensive domestic Quality System Inspection.
Acceptance Criteria	Decrease of total inspectional time.	
Summary of Results	The QSIT Study was initiated on 10/1/98. It had a target completion date of 12/31/98. This date was extended to 2/19/99 in order to allow for the completion of at least 40 total QSIT inspections. During the Study period, 12 QSIT trained investigators, 4 each in DEN-DO, LOS-DO and MIN-DO, conducted medical device Quality System inspections using the QSIT. A total of 42 inspections were conducted during the Study. Of those 42 inspections, 34 involved non-TURBO EIRs. Investigators reported their QSIT inspection time for each inspection on a CGCS. A tabulations of the reported times for the 34 non-TURBO inspections and also for the 42 total inspections are attached. The average time for conducting a QSIT inspection, based on the 34 non-TURBO inspections was determined to be 56.9 hours. The average time for conducting a QSIT inspection, based on the 42 total inspections was 55.2 hours. The average time for conducting a non-QSIT comprehensive inspection including design controls is 98.6 hours (Using PODS baseline data for PACs 82830C and 82830D). The average time for conducting a non-QSIT comprehensive inspection is 84.8 hours (Using PODS baseline data for PAC 82830C only) This equates to a 42.3% reduction (Using PODS baseline data for PACs 82830C and 82830D) or 32.9% reduction (Using PODS baseline data for PAC 82830C only) of total inspection time when using the QSIT for conducting comprehensive inspections of domestic medical device manufacturers and involving non-TURBO EIRs. This equates to a 44.0% reduction (Using PODS baseline data for PACs 82830C and 82830D) or 34.9% reduction (Using PODS baseline data for PAC 82830C only) of total inspection time when using the QSIT for conducting comprehensive inspections of domestic medical device manufacturers and involving the total 42 Study inspections.	
	The findings do [X] do not [ ] meet the acceptance criteria for this activity.	
Additional Comments		
Activity Champion(s)	Georgia Layloff (HFR-SW450) and Timothy Wells (HFZ-332)	

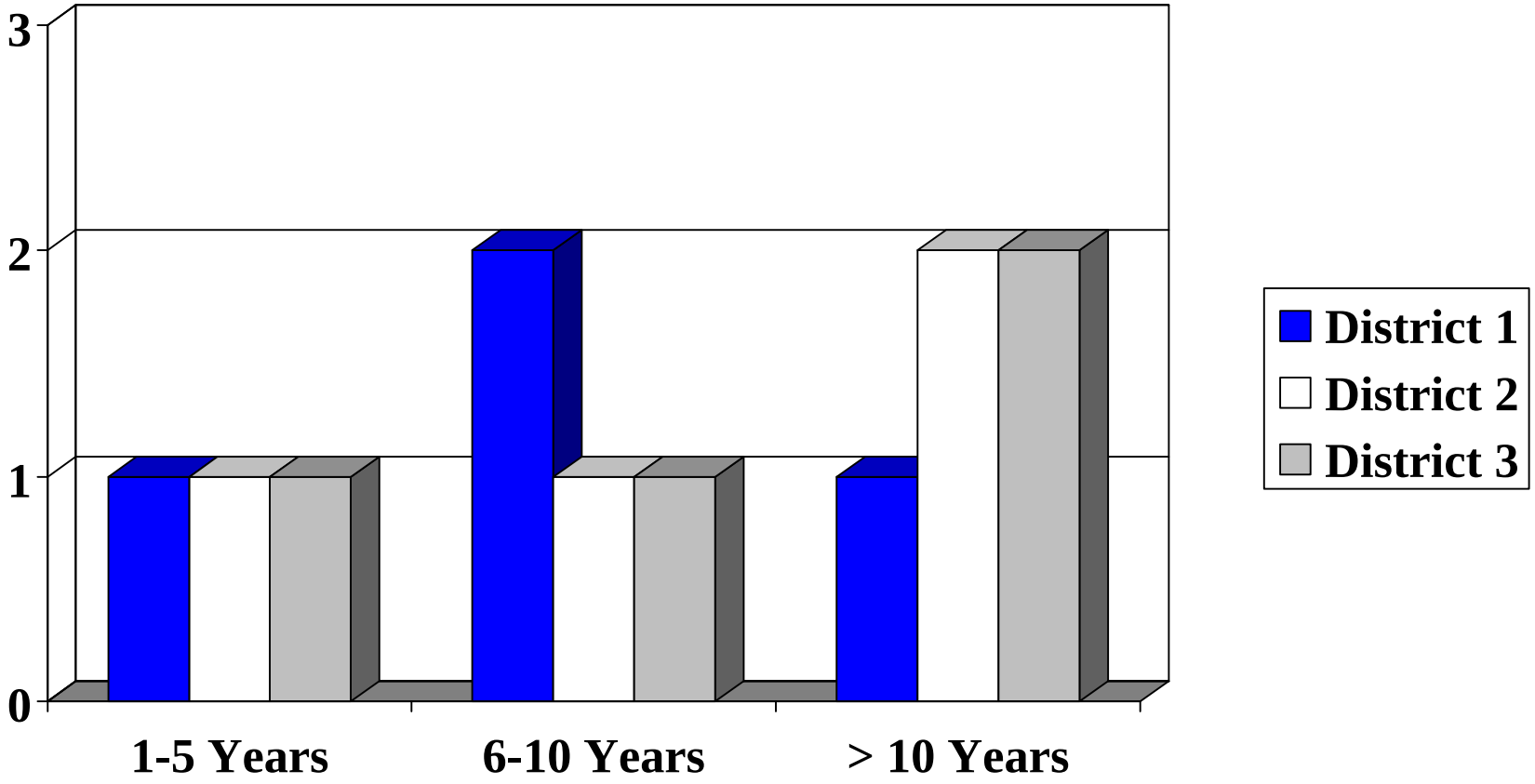
QSIT Study

- **DEN-DO, MIN-DO and LOS-DO**
  - **12 Investigators**
    - **Investigators had varying levels of experience**
  - **3 Compliance Officers**
  - **All Individuals were QSIT trained in 9/98**
- **42 Inspections**
  - **Conducted 10/1/98 - 2/19/99**

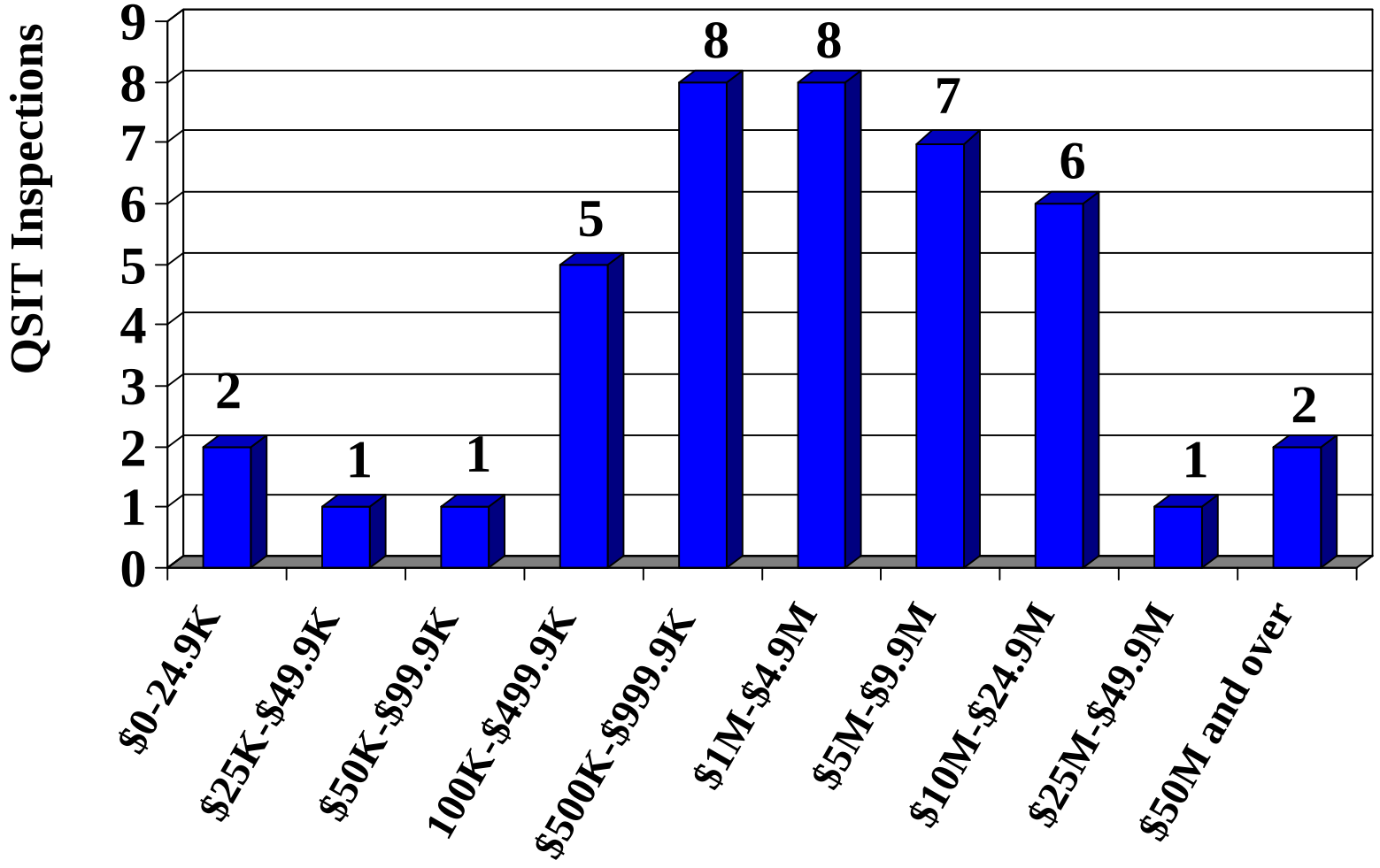
Study Demographics

- **The districts used QSIT during routine inspections of:**
  - **various types of devices**
  - **various sizes of firms**

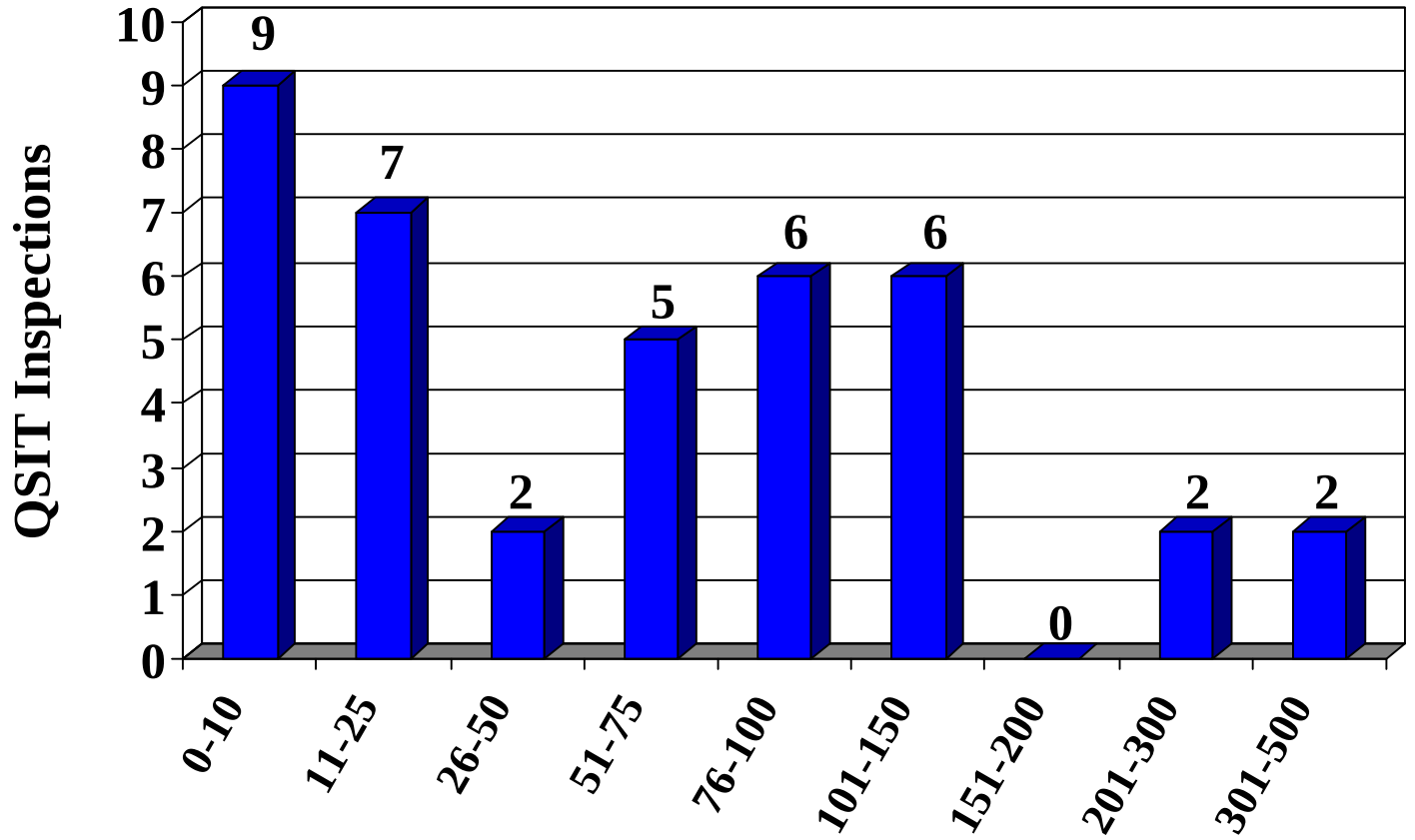
QSIT Study
Investigator Experience



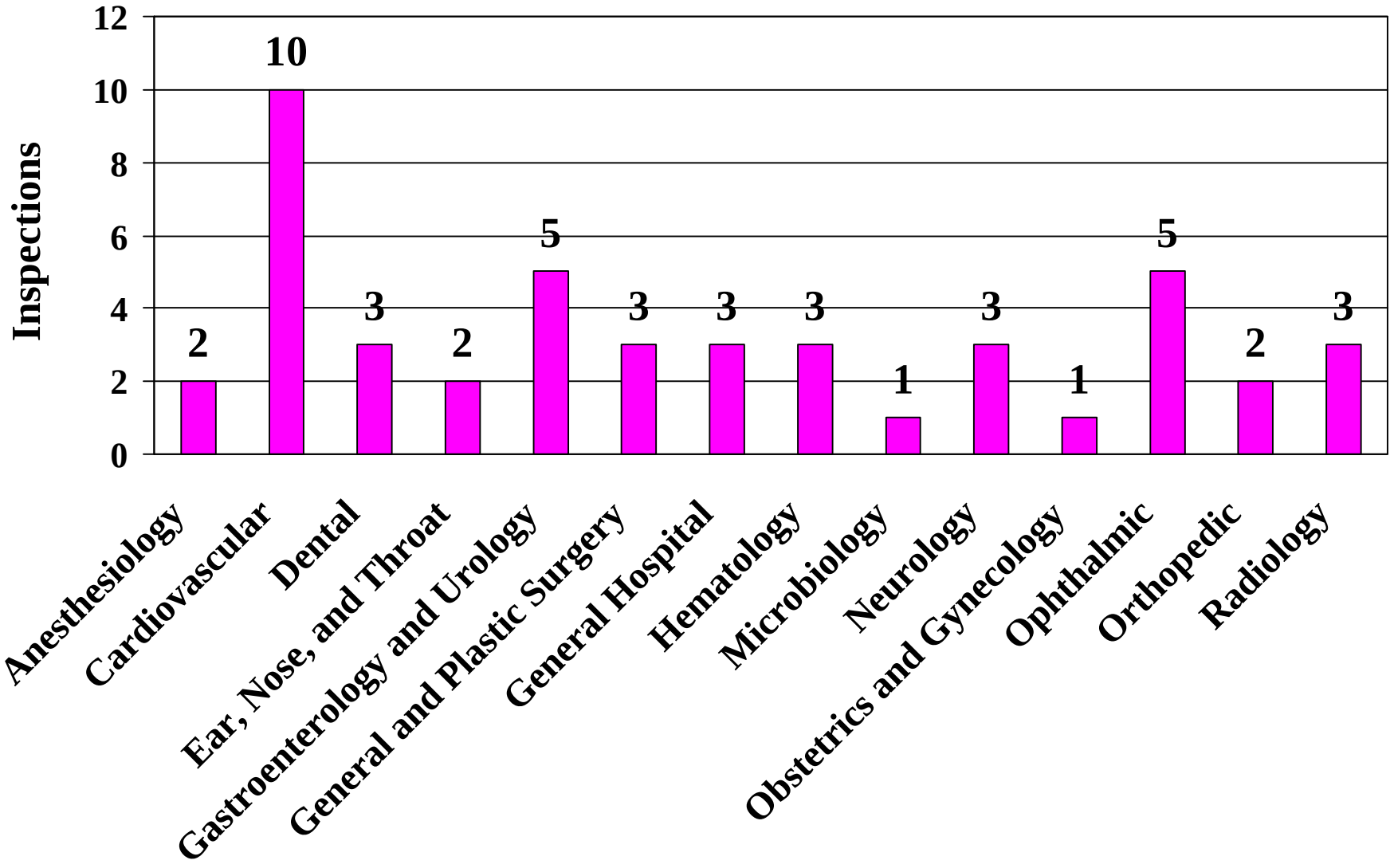
Annual Dollar Volumes
(41 of 42 Firms)



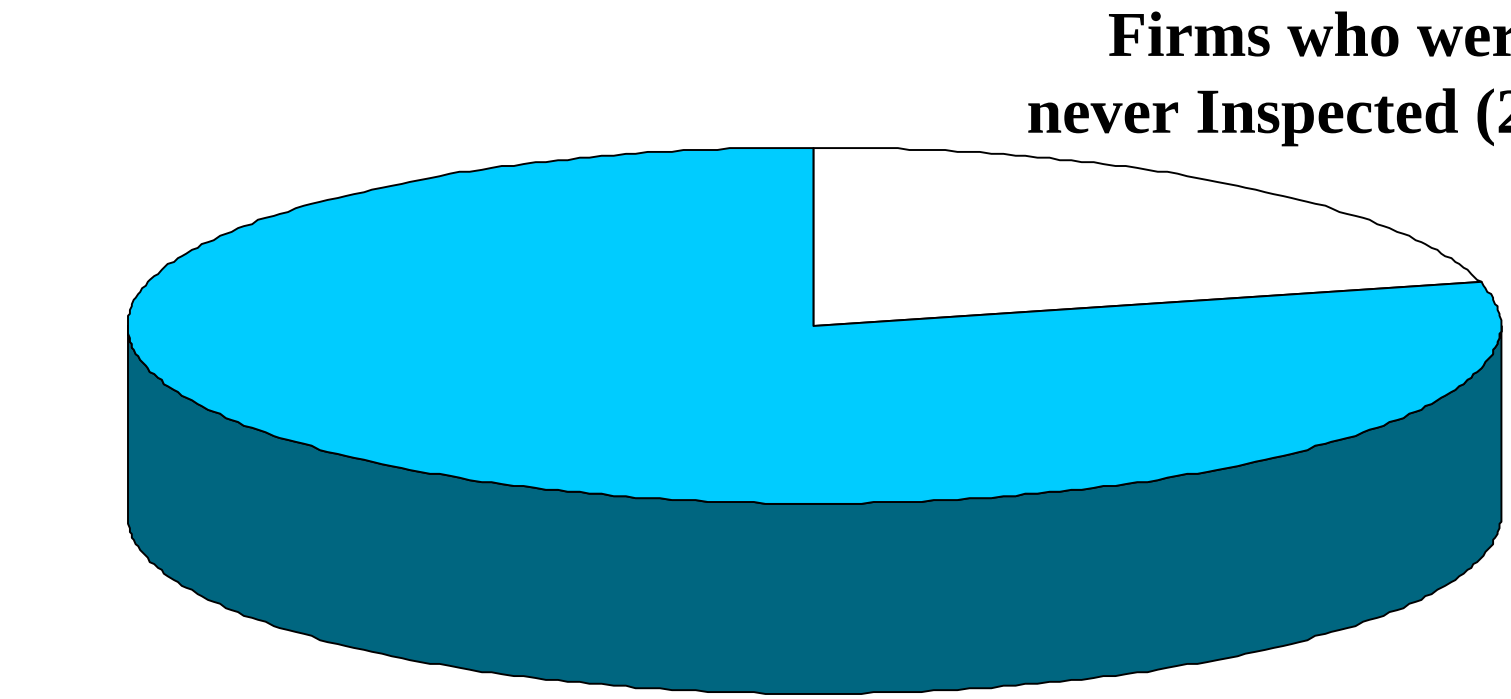
Numbers of Employees
(39 of 42 Firms)



Product Codes



Types of QSIT Inspections



QSIT Surveys/Evaluation Forms (for each QSIT Inspection)

- **Investigator and Compliance Officer**

  - The Investigator and Compliance Officer forms were submitted for each QSIT inspection

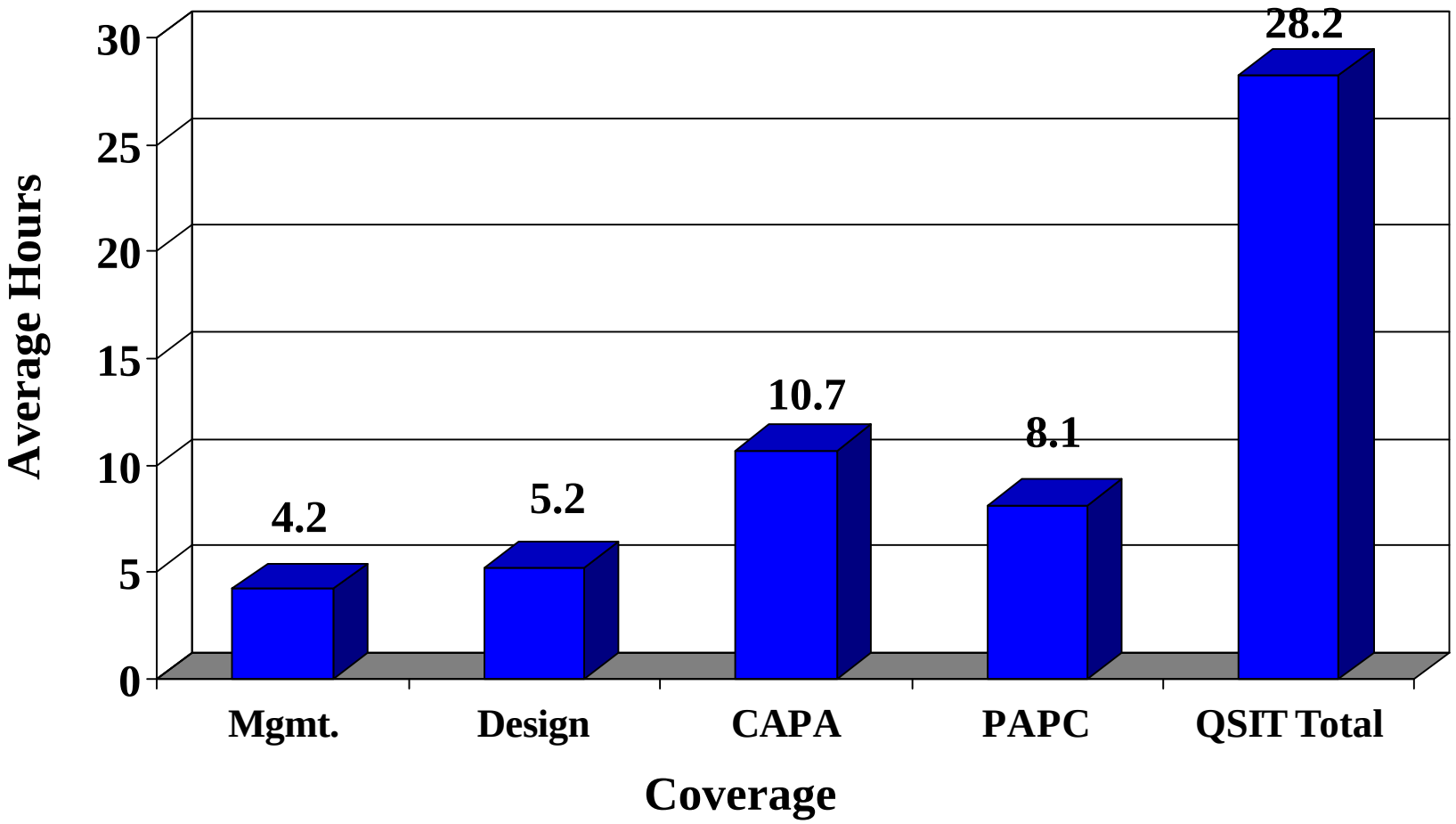
  - 100 % return rate

- **Inspected Firms**
  - **OMB approved survey forms were mailed to each QSIT inspected firm**
  - **45% return rate**

Goals of the QSIT Study

Decrease Time

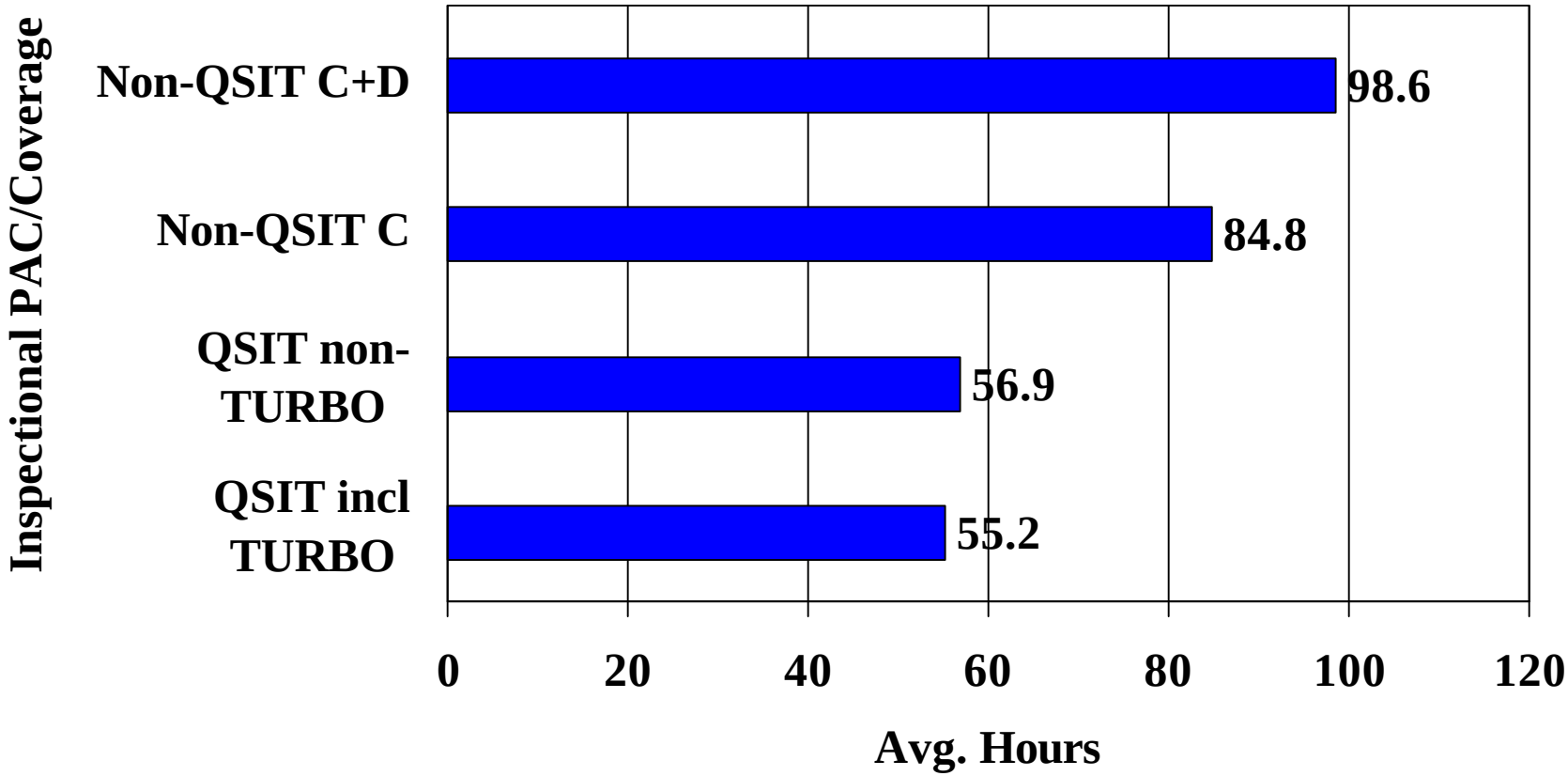
In-Plant Time
QSIT Inspections



For purposes of the study, 6 in-plant hours = one day (28.2 /6 = 4.7 days)

Decrease Total Time

QSIT vs Non-QSIT (1998 data)

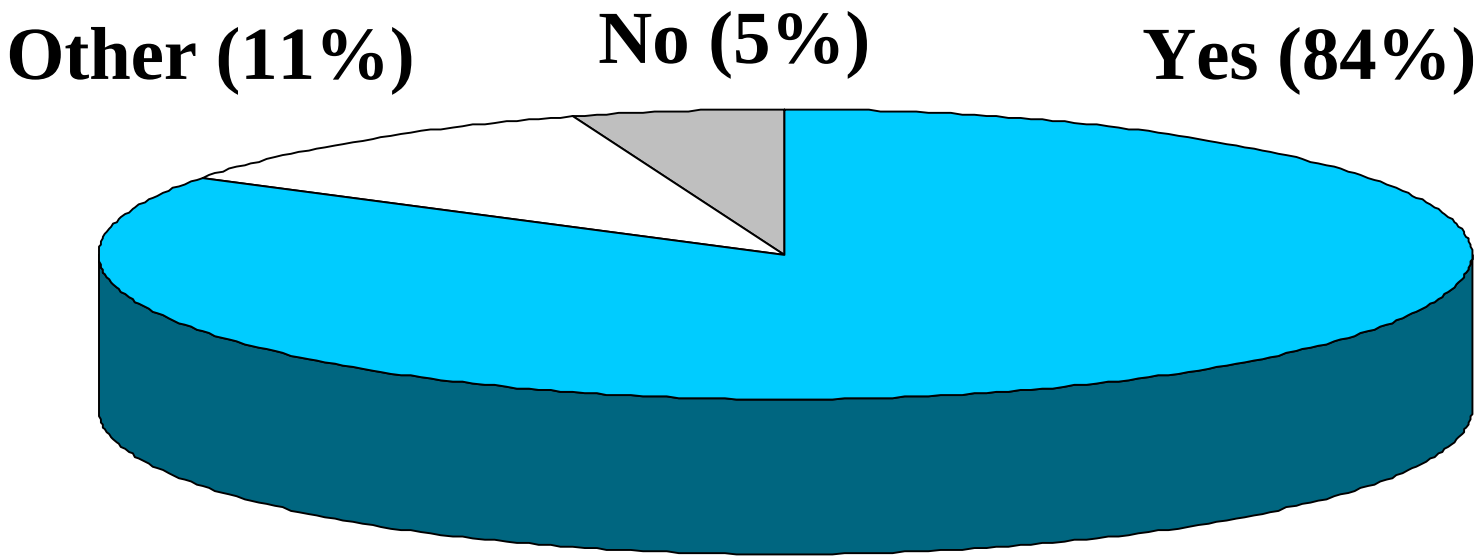


PAC Coverage, C=Comprehensive, D=Design
TURBO = TurboEIR
Total time includes preparation & write-up time

Decrease Time

Industry Survey Responses

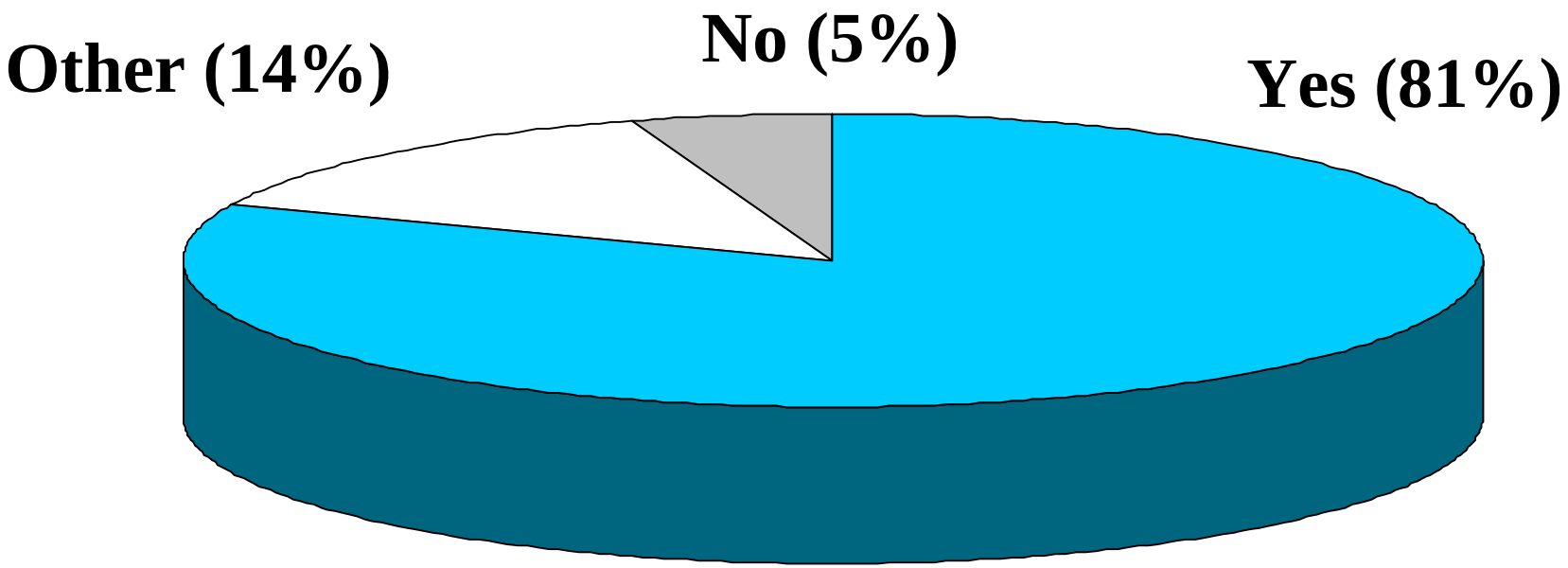
Did use of the QSIT result in a more efficient inspection by FDA?



Decrease Time

Investigator Evaluation Form Responses

Did use of the QSIT result in a more efficient inspection?



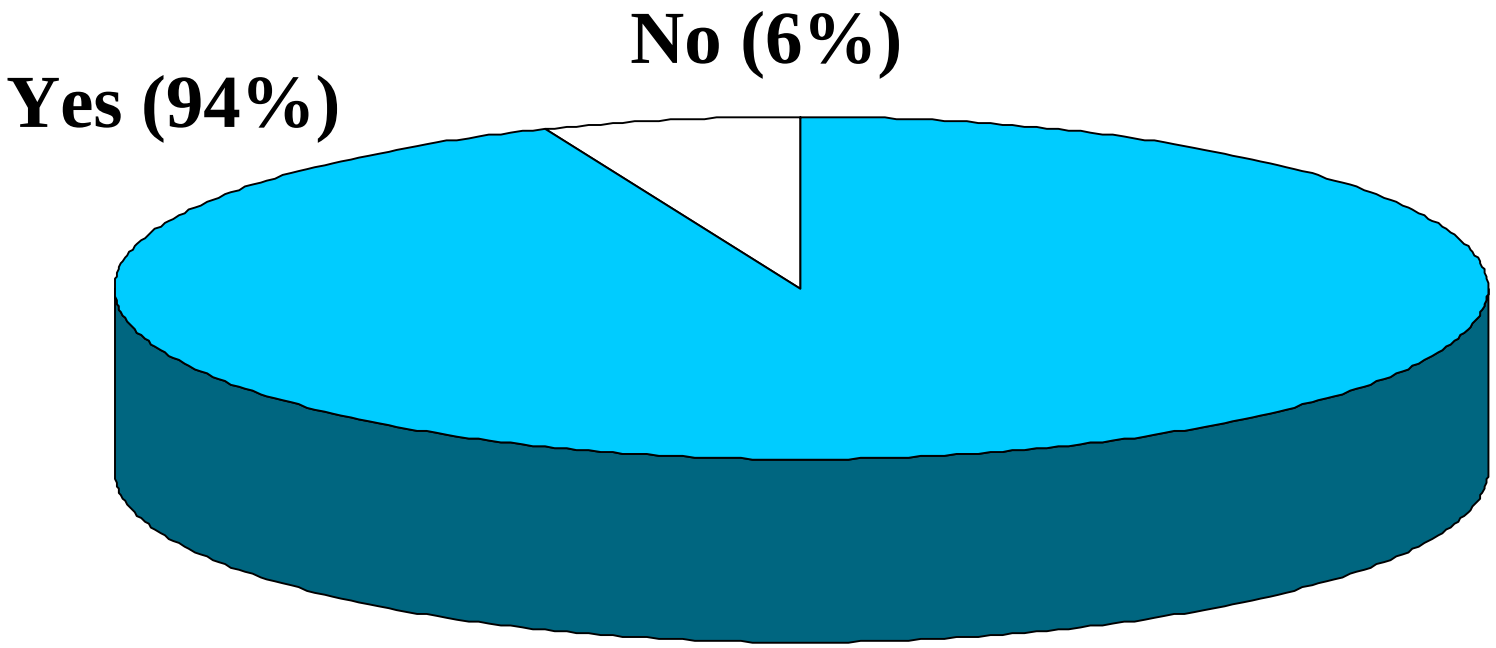
Pre-inspection Record Review

- **Conducted in 66.7% of inspections (28 of 42)**
- **Review averaged 4 hours**

(See “PREANNOUNCED INSPECTIONS” in QSIT Handbook.)

Decrease Time
Industry Survey Responses
Pre-inspection Record Review

Did providing such records facilitate the inspection process?

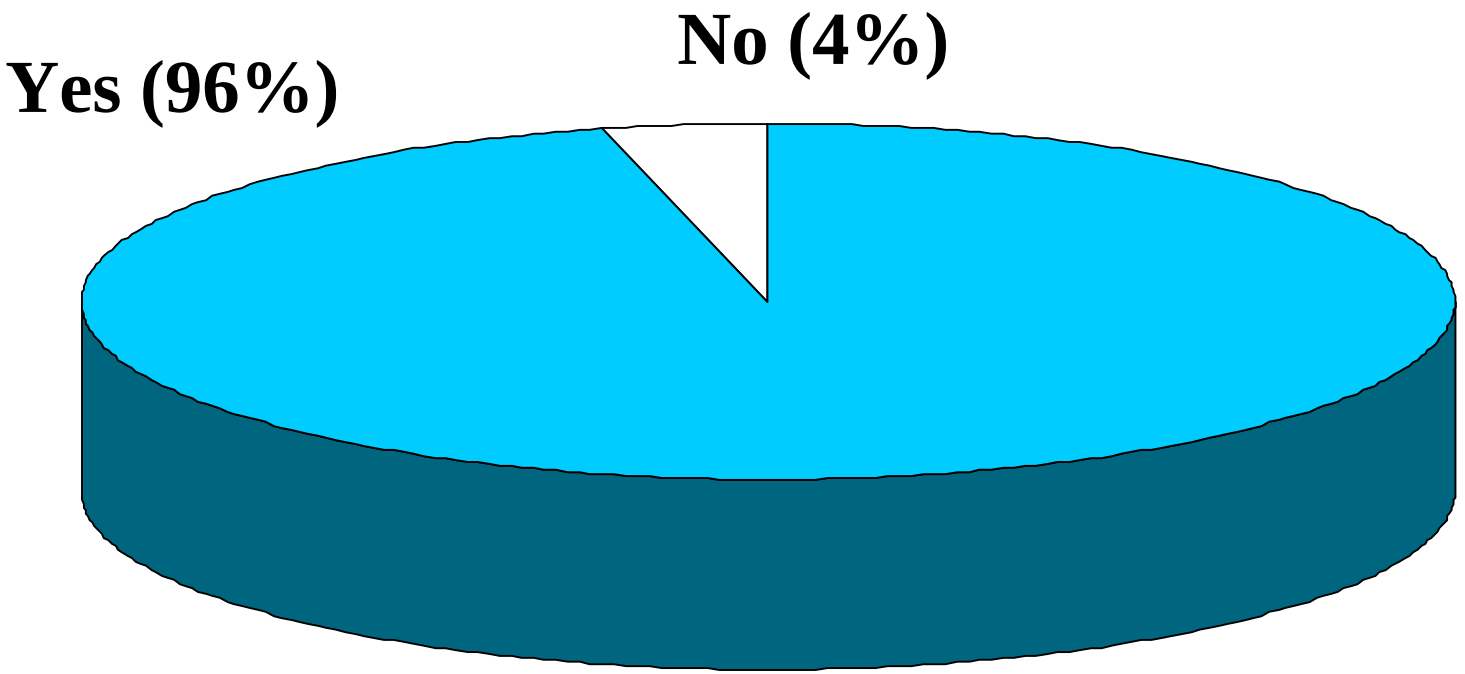


Decrease Time

Investigator Evaluation Form Responses

Pre-inspection Record Review

Did this review increase the efficiency of the inspection?

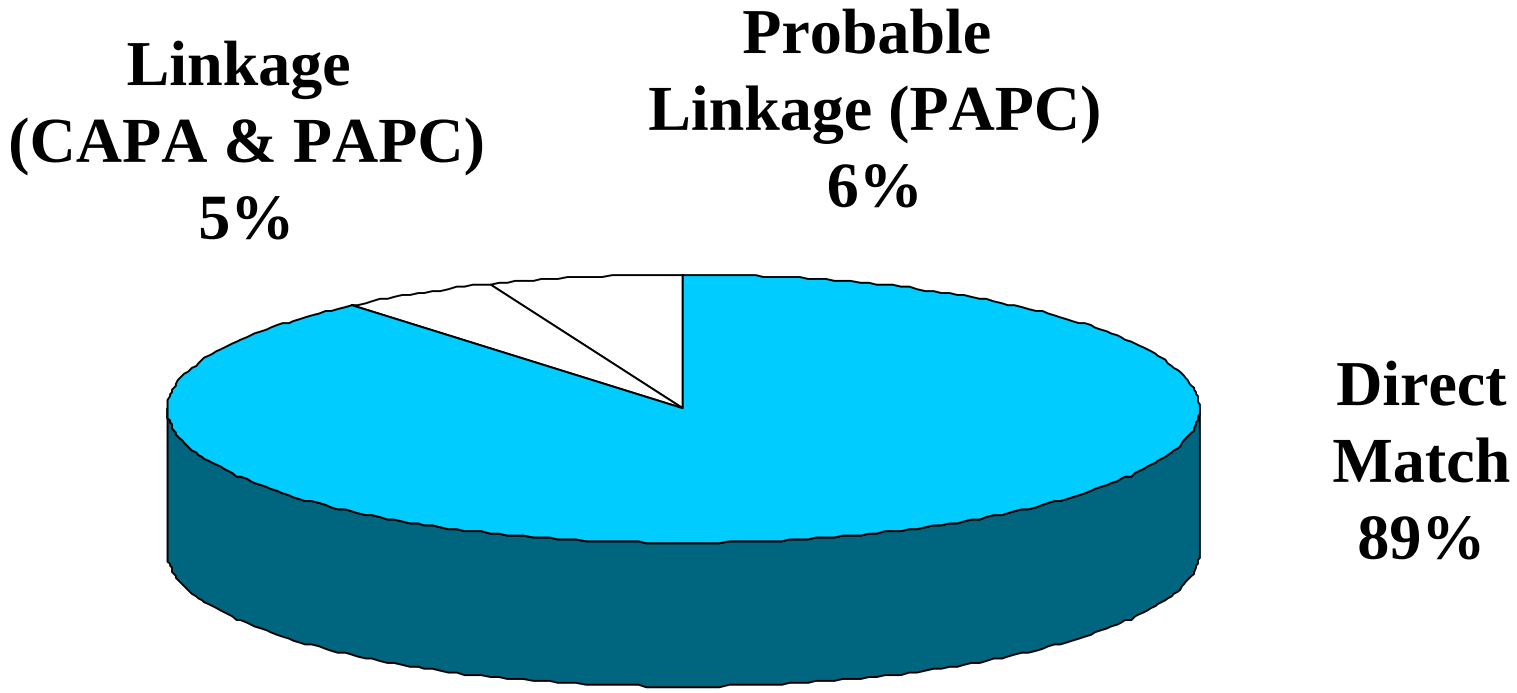


Increase Focus

QSIT Handbook

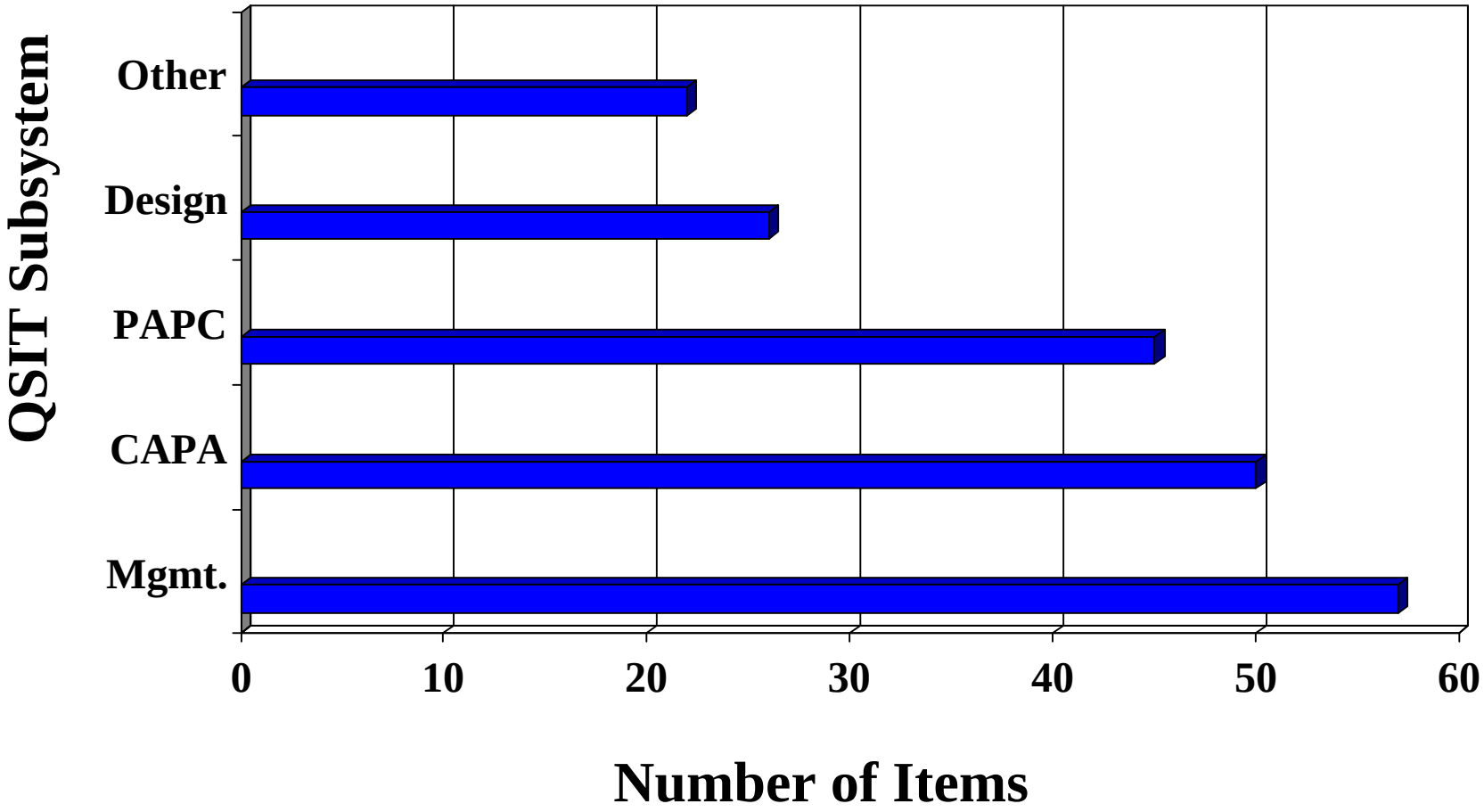
- **Developed by FDA & Industry to focus the investigators on key quality system areas**
- **Use of the handbook assures that the inspection is “focused”**
- **Handbook Sections:**
  - **Management Controls (Mgmt)**
  - **Design Controls**
  - **Corrective & Preventive Actions (CAPA)**
  - **Production & Process Controls (PAPC)**

Increase Focus FDA 483 Items from QSIT Inspections



Match of QSIT Inspection FDA 483 Items to QSIT Handbook Items

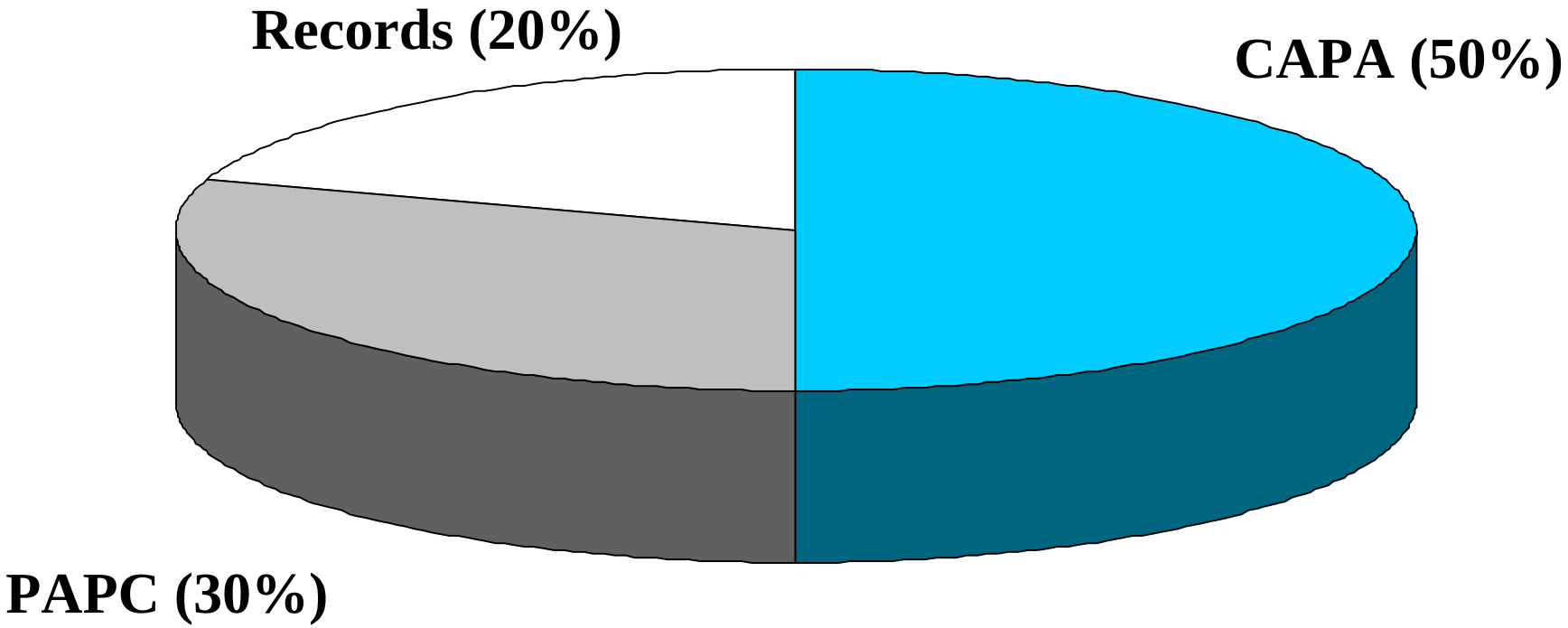
QSIT Inspections Increase Focus - FDA 483



200 Total (FDA 483) Items from QSIT inspections

Increase Focus - not using QSIT

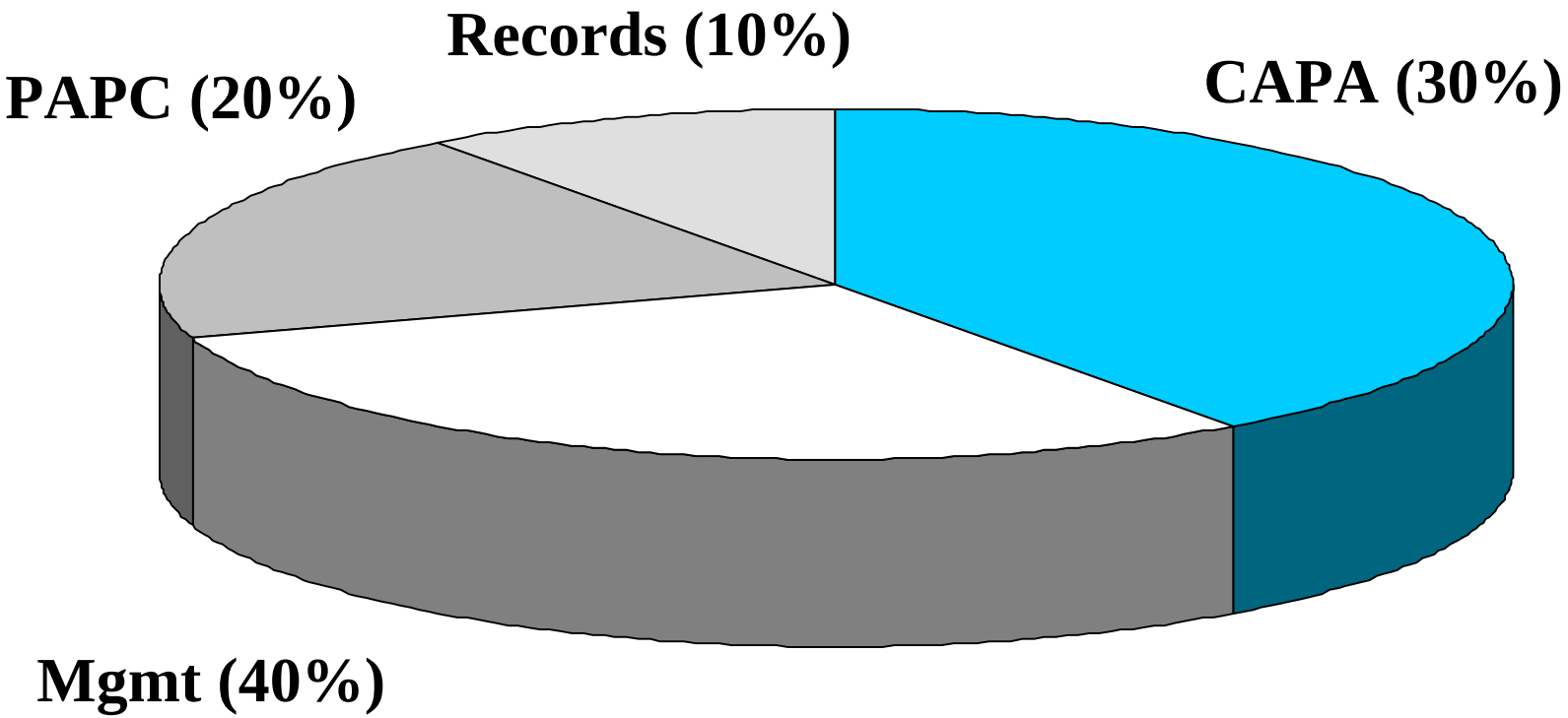
Top Ten 483 Items



Data from Non-QSIT Inspections
From CDRH database for previous 13 months

Increase Focus - using QSIT

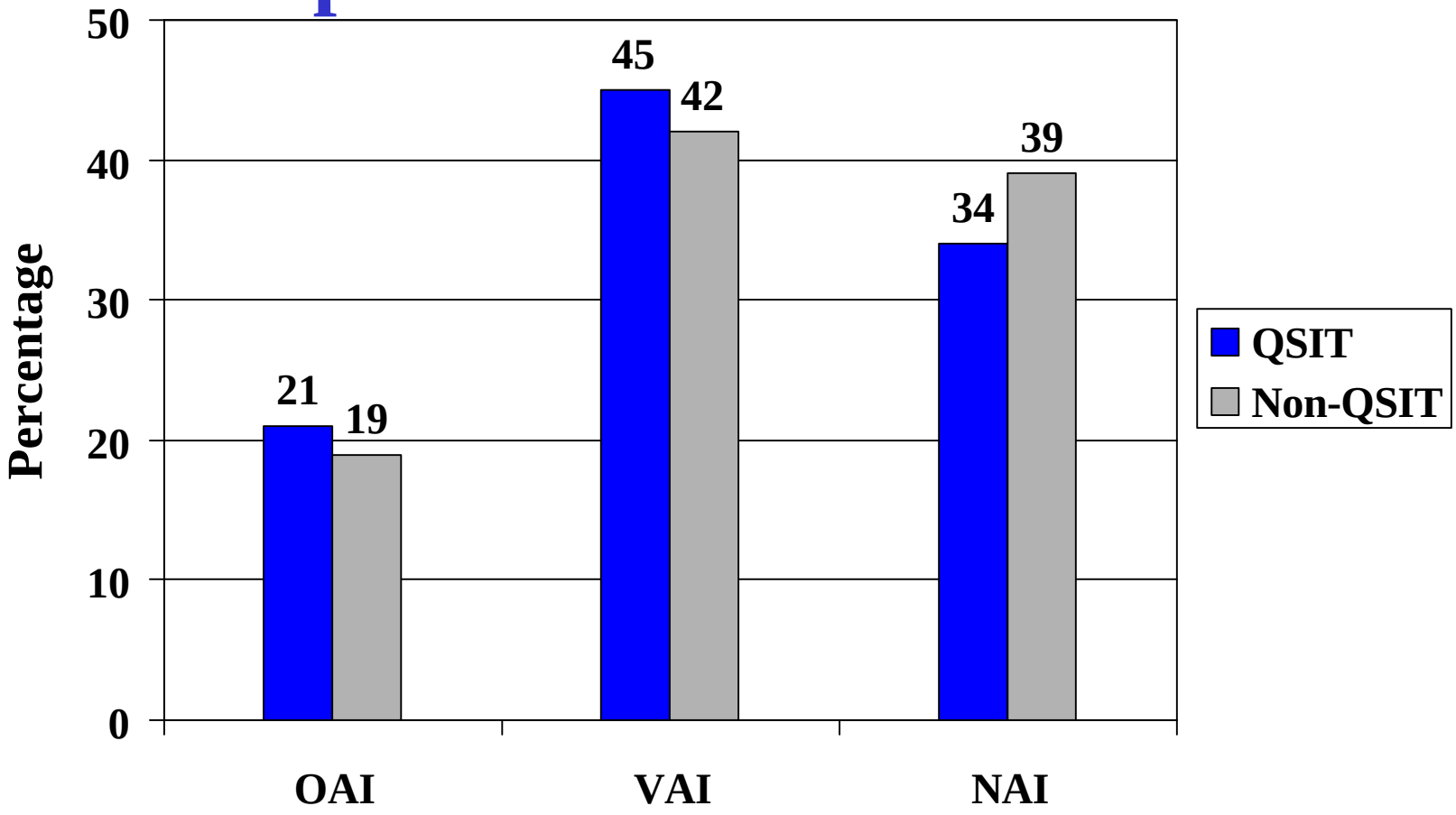
Top Ten 483 Items



Data from 42 QSIT Inspections

Increase Focus

Inspection Classifications



QSIT Inspections classified using Draft CP Part V vs FY 98 Non-QSIT inspection data
OAI=Official Action Indicated

Increase Focus

Industry Survey Responses

Did the QSIT focus on the key elements of your quality system?

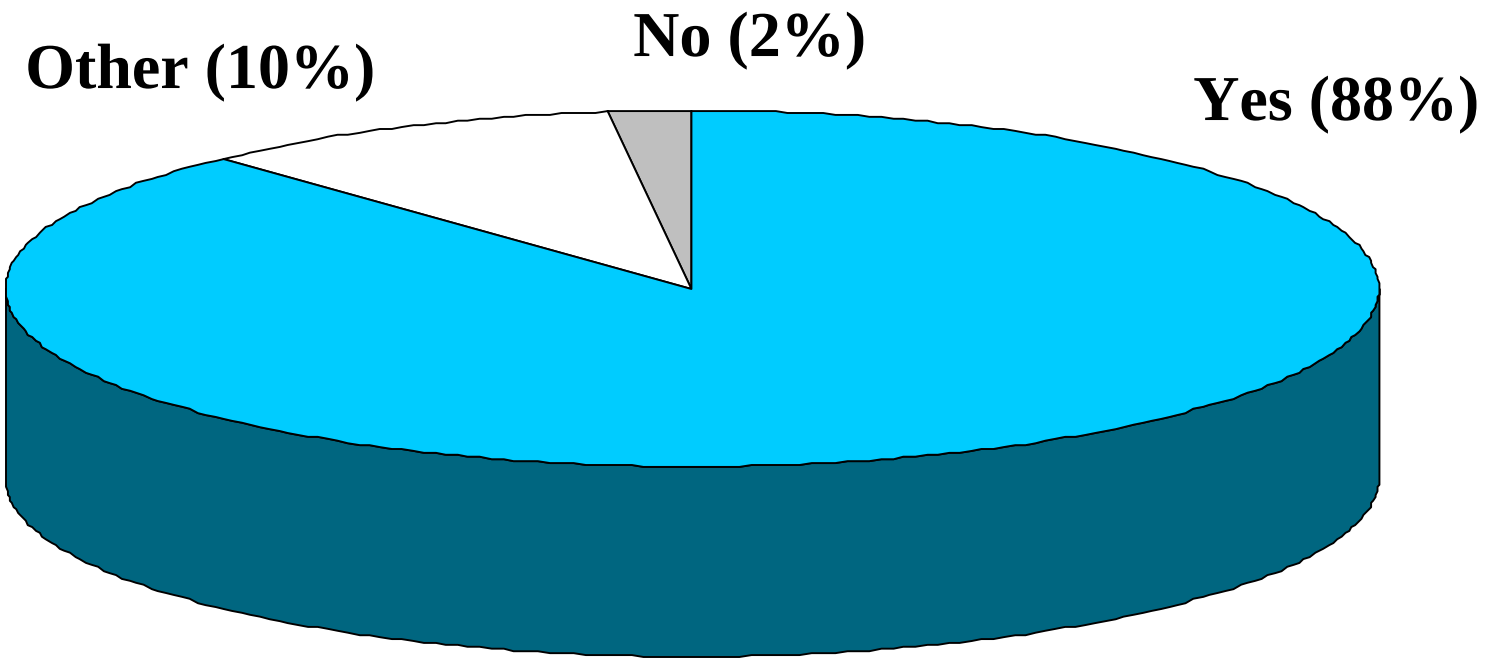
YES

100%

Increase Focus

Investigator Evaluation Form Responses

Did use of the QSIT result in a more focused inspection?



Move Towards Harmonization

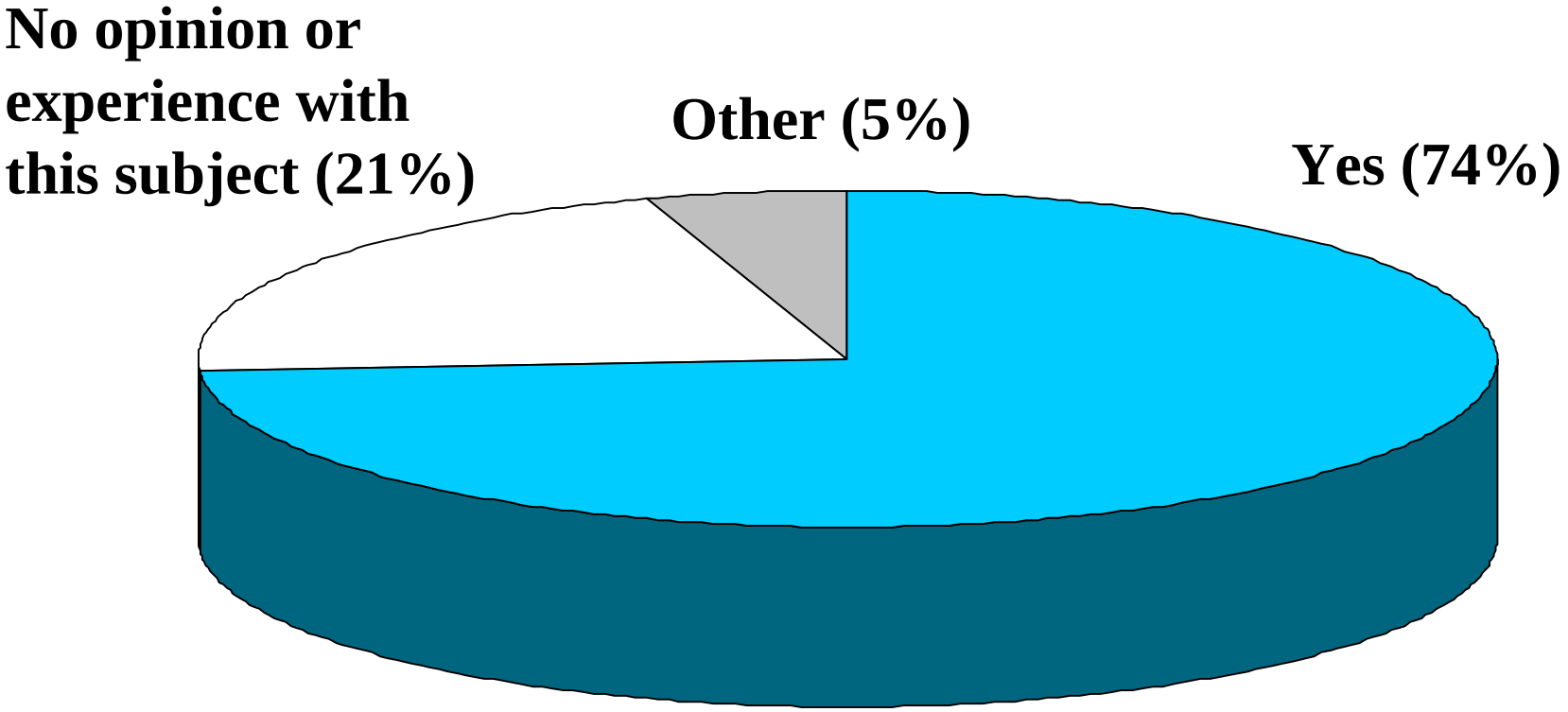
Move Towards Harmonization

- The QSIT Handbook was developed by FDA and Industry to incorporate numerous concepts from the Global Harmonization Task Force GUIDELINE FOR REGULATORY AUDITING OF QUALITY SYSTEMS OF MEDICAL DEVICE MANUFACTURERS.
- Use of the handbook assures that the inspection is “moving towards harmonization”

Move Towards Harmonization

Industry Survey Responses

Did you find the QSIT approach similar to that used by auditing organizations utilized by your firm?



Ensure QSIT Handbook provides QS Regulation Coverage

- Gap Analysis of QSIT Handbook was performed by FDA and Industry
- QSIT Handbook was ammended when gaps were identified

Quality System Regulation	CSO Nelson's Alignment	QSIT Coverage	Comments
820.1(a)-(e) Scope	No	No	Training issue
820.3 (a) –(aa) Definitions	No	No	Training issue
820.5 Quality System	Yes	Yes ("Getting Started")	Confirmation is an ultimate goal of QSIT
820.20 Management Respon.	Section Title	Section Title	
820.20(a) Quality Policy	Yes	Yes (MCO1, MCO2)	
820.20(b) Organization	Yes	Yes (MCO3, MCO4)	
820.20(b)(1) Resp. and Auth.	Yes	Yes (MCO3)	
820.20(b)(2) Resources	Yes	Yes (MCO3)	
820.20(b)(3) Management Rep.	Yes	Yes ("Getting Started", MCO4)	
820.20(c) Management Review	Yes (Mgt and Fac. & Equip.)	Yes (MCO1, MCO5, CAPAO10)	
820.20(d) Quality planning	Yes	Yes (MCO1)	
820.20(e) Quality system proc.s	Yes	Yes (MCO1)	
820.22 Quality Audit	Yes	Yes (MCO6)	
820.25 Personnel	Section Title	Section Title	
820.25(a) General	Yes	Yes (P&PCO6L, SPCO5L)	
820.25(b) Training	Yes (Mgt and P&PC)	Yes (P&PCO6, SPCO5)	
820.30 Design Control	Section Title	Section Title	
820.30(a) General	Yes	Yes (DCO1)	
820.30(b) Design and Dev. Plan.	Yes	Yes (DCO3)	
820.30(c) Input	Yes	Yes (DCO2, DCO4)	
820.30(d) Output	Yes	Yes (DCO2, DCO4)	
820.30(e) Review	Yes	Yes (DCO2, DCO4)	
820.30(f) Verification	Yes	Yes (DCO2, DCO6, DCO7)	
820.30(g) Validation	Yes	Yes (DCO2, DCO6, DCO8 - DCO12)	
820.30(h) Transfrer	Yes	Yes (DCO2, DCO15)	
820.30(i) Changes	Yes (Doc. & Change Control)	Yes (DCO2, DCO13)	
820.30(j) DHF	Yes (Doc. & Change Control)	Yes (DCO2)	Change FC Box 2 (documented Proc.s not required for DHF) add statement re: DHF to narrative of DCO2
820.40 Document Controls	Yes	Yes (P&PCO2L, SPCO2L)	
820.40(a) Approval and Distrib.		Yes (P&PCO2L, SPCO2L)	
820.40(b) Changes	Yes	Yes (P&PCO2L, SPCO2L)	
820.50 Purchasing Controls	Yes	Yes (P&PCO2, SPCO2)	Add 820.50 cite to P&PC and SPC FC Box (2)
820.50(a) Evaluation of Suppliers	Yes	Yes (P&PCO2, SPCO2)	Add 820.50(a) cite to P&PC and SPC FC Box (2)
820.50(b) Purchasing data	Yes	Yes (P&PCO2, SPCO2)	Add 820.50(b) cite to P&PC and SPC FC Box (2)
820.60 Identification	Yes	No	Add as linkage to P&PCO2 & SPCO2
820.65 Traceability	Yes	No (indirectly through review of DHR)	Add as linkage to P&PCO2 & SPCO2
820.70 P&PC	Section Title	Section Title	
820.70(a) General	Yes	Yes (P&PCO2, SPCO2)	
820.70(b) Changes	Yes (Doc. & Change Control)	Yes (DCO13, P&PCO2L, SPCO2L)	Add Linkage to DCO13, add statement to P&PCO2 and SPCO2 narrative to confirm process changes are handled appropriately, add 820.70(b) cite to P&PC and SPC FC's

Outcomes of the QSIT Study

Increase Consistency

Increase Consistency

- **QSIT provides a methodology for inspection, which is:**
  - **well defined**
  - **succinct**
  - **prescriptive**
- **This methodology will help ensure consistency**

Increase Consistency

- **Comparison of 200 FDA 483 Items from the study to the QSIT handbook**
  - **178 FDA 483 Items match directly to the QSIT flowchart in the handbook**
  - **22 FDA 483 Items were linkages to the QSIT handbook**
- **This comparison demonstrates consistency**

Same data used here as in the “Increase Focus FDA 483 Items” slide

Improve Review Efficiency

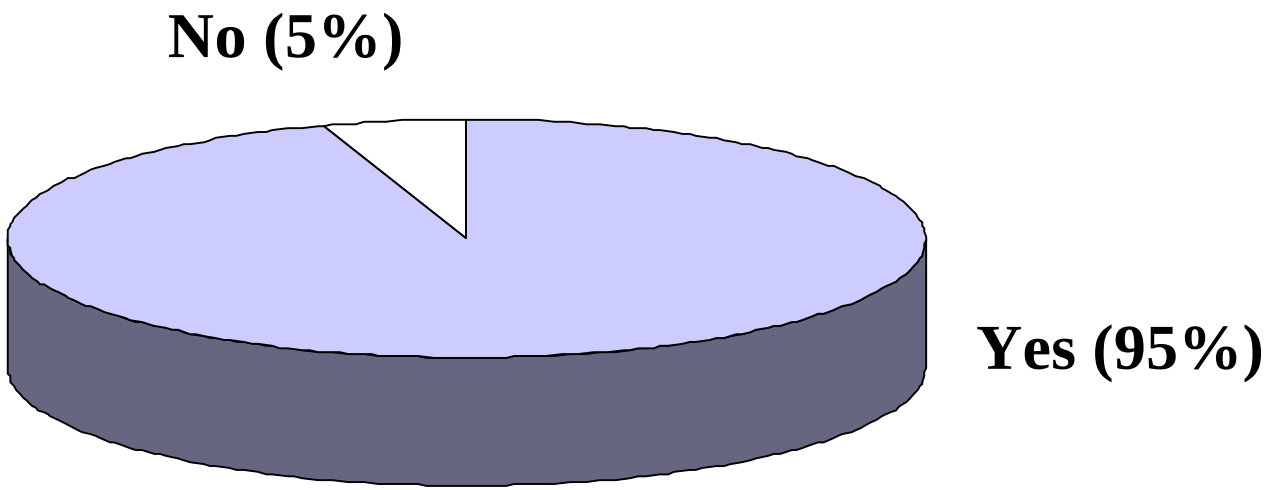
Improve Review Efficiency
Compliance Officer Survey Responses

- **Did the QSIT approach generally result in an EIR which was better organized and easier to review and evaluate? (3.75)**
- **Did the QSIT approach result in an EIR of generally higher quality? (3.25)**
- **Did the QSIT approach result in more thorough documentation of violations? (3.25)**

[Answer scale: 0 (do not agree) - 5 (strongly agree)]

Improve Review Efficiency

Compliance Officer Evaluation Form Responses



Did the investigator's focus on key areas help make your review easier?

Improve Review Efficiency

Compliance Officer Survey Responses

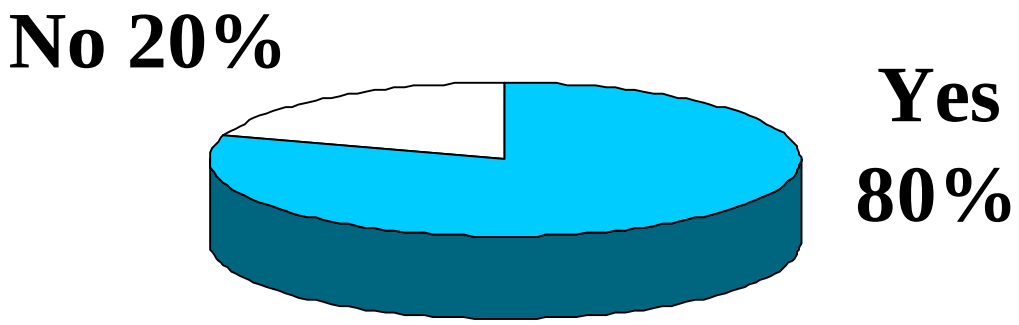
- **Did QSIT affect the time needed to review the EIR? (4.0)**

[Answer scale: 1 (much longer) - 5 (much quicker)]

Other Industry Survey Responses

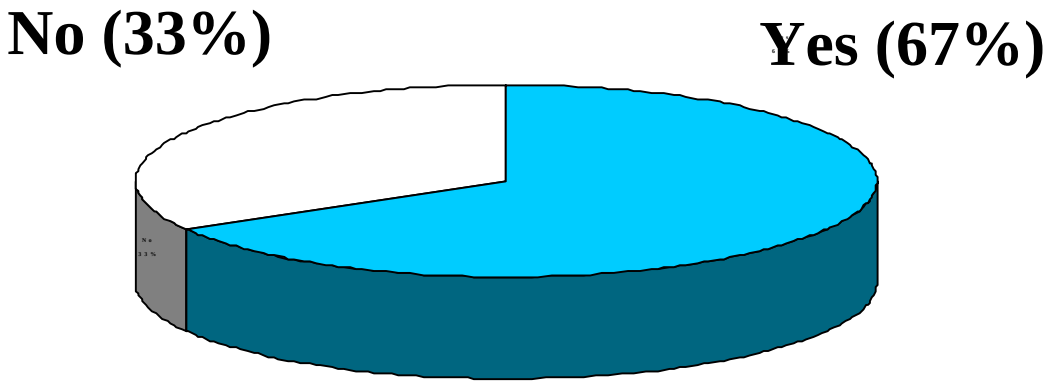
Note: Individual comments are available to review. Some comments with the “no” answers stated that compliance and product quality was already high, thus QSIT will not increase compliance or quality.

Industry Survey Responses



Do you think that use of the QSIT will result in improved compliance of the medical device industry with the Quality System regulation?

Industry Survey Responses



Do you think that use of the QSIT will result in an improvement of the quality of medical devices produced by the medical device industry?

Industry Survey Responses

Do you think that the use of the QSIT will increase the medical device industry's knowledge and understanding of the requirements of the Quality System Regulation?

YES

100%